

**9 510(K) SUMMARY**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and CFR 21 §807.92.

**Submitter's Information:**

Name: RADI Medical Systems AB  
 Address: Palmbladsgatan 10, SE-754 50 Uppsala, Sweden  
 Phone/Fax: +46-18-161000 / +46-18-161099  
 Contact Person: Mats Granlund  
 Date of Preparation: October 5, 1998

**Device Name:**

Trade Names: PressureWire™ Sensor  
 Common Name: Pressure Guidewire  
 Classification Name: Catheter Guide Wire (870.1330)  
 Catheter Tip Pressure Transducer (870.2870)

**Predicate Device Names:** PressureWire™ Sensor (K972793)

**Device Description:**

The PressureWire™ Sensor consists of a pressure sensor mounted steerable guidewire to perform real-time invasive pressure measurement in the vasculature and a detachable cable for connection to RADI Medical Systems PressureWire™ Interface only.

The guidewire has an outer diameter of .014" and is 175 cm in length. The pressure sensor is mounted just proximal of the 3 cm shapeable radiopaque tip.

PressureWire™ Sensor is connected to the PressureWire™ Interface via the Interface Cable which has an identification memory chip containing the individual calibration parameters for the sensor.

The readings from the PressureWire™ Sensor and the one measured through a guiding catheter can be used as input for calculation of various indices which require one or two input values e.g. gradient or Fractional Flow Reserve (FFR) etc.

**Intended Use:**

PressureWire™ Sensor is intended to provide pressure signals from the coronary and peripheral vessels and to guide the positioning of interventional devices.

**Technical Characteristics Summary:**

The technical characteristics of PressureWire™ Sensor is almost identical with the predicate device.

**Performance Data:**

Due to the extreme similarity in design and materials between subject and predicate devices further product performance testing has not been considered necessary. A bench test have been conducted to show that the presence of the PressureWire Sensor within a guiding catheter (6 Fr. or greater) does not clinically significant impact the pressure signal recorded by the catheter

**Conclusions**

The device is almost identical with predicate device and found to be suitable for its intended use.



FEB 3 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mats Granlund  
RADI Medical Systems AB  
Palmladsgatan 10, SE-754  
50 Uppsala, Sweden

Re: K983506  
Trade Name: Pressure Wire™ Sensor  
Regulatory Class: II  
Product Code: DQX  
Dated: December 21, 1998  
Received: December 23, 1998

Dear Mr. Granlund:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

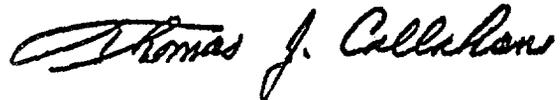
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to

your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory  
And Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Statement of Indications for Use

510(k) Number: K983506

Device Name: PressureWire™ Sensor

Indications for Use: The PressureWire Sensor is intended for use in coronary and peripheral blood vessels to measure blood pressure during percutaneous procedures and to facilitate the placement of interventional devices.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K983506

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use  OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1/2/96)